



TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
FLH-11702/29

NAME & TRADEMARK OFFICE
Re Application Of: Falahee

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/807,999	03/24/2004	E. Robert	25006	3732	4663

Invention: **LOW PROFILE SCREW ANCHOR WITH VARIABLE AXIS/ANGLE FIXATION**

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

July 26, 2005

Applicant claims small entity status. See 37 CFR 1.27

The fee for filing this Appeal Brief is: \$250.00

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Signature

Dated: Sept. 26, 2005

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CC:

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

Sept. 26, 2005

(Date)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Falahee *Atty. Docket No. FLH-11702/29*

Serial No.: 10/807,999 Group No.: 3732

Filed: March 24, 2004 Examiner: Eduardo C. Robert

For: LOW PROFILE SCREW ANCHOR WITH VARIABLE AXIS/ANGLE FIXATION

APPELLANT'S BRIEF UNDER 37 CFR §1.192

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party and interest in this case is Medical Designs, LLC, by assignment.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 13 claims. Claim 2 was canceled by amendment in February 2005. Claim 13 was canceled by amendment attached hereto. Claims 1 and 3-12 are pending, rejected and under appeal. Claims 1, 6 and 9 are the independent claims.

IV. Status of Amendments Filed Subsequent Final Rejection

An after-final amendment is attached hereto.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed to an orthopaedic fixation system, comprising a bone anchor having proximal and distal ends and outwardly advancing tangs or barbs to assist with fixation; and a connector having portion that engages with the bone anchor once in position and an arm that engages with an existing stabilizing rod. (Specification, page 3, lines 12 to 27; Figures 1-3)).

Independent claim 6 is directed to an orthopaedic fixation system, comprising a bone anchor having proximal and distal ends and wherein the proximal end is substantially at the surface of a bone once in position; and a connector having portion that engages with the bone anchor once in position and an arm that engages with an existing stabilizing rod. (Specification, Claim 3 as originally filed; Figure 7).

Independent claim 9 is directed to an orthopaedic fixation system, comprising a bone anchor having proximal and distal ends; and an elbow having portion that engages with the bone anchor once in position and an arm that engages with an existing stabilizing rod. (Specification, page 4, lines 8 to 18; Figures 5 and 6).

VI. Grounds of Objection/Rejection To Be Reviewed On Appeal

A. The rejection of claims 6, 8, 9 and 11-13 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,648,388 to Steffee.

B. The rejection of claims 1, 3-5, 7 and 10 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,648,388 to Steffee in view of U.S. Patent No. 324,768 to Hunt.

VII. Argument

A. The rejection of claim 6 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,648,388 to Steffee.

Claim 6 includes the limitation of a bone anchor having a proximal end which is substantially at the surface of a bone once in position. The Examiner rejects on the grounds that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations of that claimed, citing Ex parte Masham, 2 USPQ 1647, 1648 (Bd. Pat. App. & Int. 1987). Appellant traverses on several

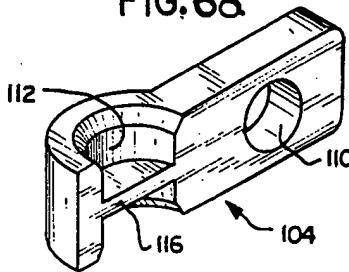
grounds. First, the language of the claim clearly establishes a structural relationship, and not a mere "intention to be employed" limitation. The claim sets forth "a bone anchor having proximal and distal ends and wherein the proximal end is substantially at the surface of a bone once in position." Thus, the claim requires "a bone anchor having [a] proximal ... end" (a structural limitation), and wherein this particular structure is "substantially at the surface of a bone once in position" (another structural relationship).

Secondly, it is clear that if the cited prior-art were to meet the structural limitations of Appellant's claim 6, the prior art would be rendered non-utilitarian. According to Steffee, a "force transmitting member (52)" is introduced into a vertebral body such that a threaded portion remains exposed (col. 3, line 38 to col. 4, line 4). If the member were screwed in entirely, as the Examiner suggests, there would be nothing to attach to and the system would not work. Anticipation may be established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Systems, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Moreover, anticipation requires the presence of all elements of a claimed invention as arranged in the claim, such that a disclosure "that 'almost' meets that standard does not 'anticipate'." Connell v. Sears, Roebuck Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Since the system of Steffee cannot have "a bone anchor having [a] proximal ... end [that is] substantially at the surface of a bone once in position," the cited reference cannot anticipate. The claims which depend from claim 6 are therefore allowable as well.

B. The rejection of claims 8 and 9 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,648,388 to Steffee.

In addition to other limitations, claims 8 and 9 include the limitation of "an elbow." The Examiner's only evidence is that "Steffee clearly shows what can be considered to be an elbow, e.g., part 104." This argument is flawed. First, the language "can be considered" raises the question "considered by whom?" One of skill in the art? The Examiner? Regardless, no evidence is provided. Second, "part 104" is shown below. It is not an "elbow." Rather, and according to the reference itself, part 104 is half of a "two-piece clamp 100" (col. 6 lines 57 to 63). Thus, anticipation is precluded.

FIG. 6a.



Although the Examiner rejected this claim under 35 U.S.C. §102(b) over Steffee, no reason was given and, in fact, the bone anchor of Steffee extends way beyond a bone surface, thereby precluding anticipation. The same holds true of claim 9. Although this was rejected under 35 U.S.C. §102(b) over Steffee, Steffee neither teaches nor suggests “an elbow,” such that anticipation is not established. The claims which depend from claim 9 are therefore allowable as well.

C. The rejection of claims 1 and 10 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,648,388 to Steffee in view of U.S. Patent No. 324,768 to Hunt.

Claims 1 and 10 include the limitation of a bone anchor having proximal and distal ends and outwardly advancing tangs or barbs to assist with fixation. These claims stand rejected under 35 U.S.C. §103(a) over Steffee ('388), in view of Hunt ('768). The Examiner argues that it would have been obvious “to construct the system of Steffee with the screw of Hunt in order to lock the screw in position as preventing that it is removed.” Applicant respectfully disagrees.

In this case, Steffee discusses a fastener beginning at column 3, line 37 to column 4, line 4, and nowhere does Steffee teach or suggest the need or even the desirability of tangs or barbs to assist with fixation. Likewise, Hunt is entirely silent with respect to orthopaedics in general, bone anchors in particular. Indeed, Hunt resides in a wood screw. In rejecting claims under 35 U.S.C. §103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A *prima facie* case of obviousness is established by presenting evidence that the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed combination or other modification. See In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

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Rejections based on §103 must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. The examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis for the rejection. See *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 177 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). It is well-settled that an Examiner may not resort to hindsight by using an applicant's disclosure as a blueprint to reconstruct the claimed invention from the isolated teachings of the prior art. See, e.g., *Grain Processing Corp. v. American Maize-Products Co.*, 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir., 1988). This is *precisely* what the Examiner is attempting in this case.

Moreover, Hunt represent *non-analogous art*. Although this argument is often difficult for an applicant to win, in this case the teachings of Hunt simply do not apply. The Examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992).

Here, Steffee is concerned with maintaining vertebrae in a desired spatial relationship, whereas Hunt is concerned that vessels containing articles of merchandise are fraudulently opened during transportation, and that other times, their contents pilfered (column 1, lines 19-23). Thus, the reference is not in Applicant's field of endeavor and is not reasonably pertinent to the particular problem with which the inventor was concerned, namely, in combination, an orthopaedic fixation system.

The Examiner argues that the inventor's field of endeavor is "screws and clamps and rods." This is far too broad. Rather, the inventor's field of endeavor is "bone anchoring, and in particular, a low-profile anchoring system particularly suited to pelvis fixation." (see Appellant's Field of the Invention.) Hunt's field of endeavor is, perhaps, "anti-tampering." The Examiner goes on to state that "Steffee and Hunt are related to the field of screws and how they are designed to function to attach and be attached to other structures." Apart from again being overly broad, Appellant is not arguing that Steffee is non-analogous; rather, that a person of skill *in the relevant art* would never find, refer to, or

consider the teachings of Hunt. The claims which depend from claim 1 are therefore allowable as well.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Date: Sept. 26, 2005

Respectfully submitted,

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APPENDIX A

CLAIMS ON APPEAL

1. An orthopaedic fixation system, comprising:
a bone anchor having proximal and distal ends and outwardly advancing tangs or barbs to assist with fixation; and
a connector having portion that engages with the bone anchor once in position and an arm that engages with an existing stabilizing rod.

3. The orthopaedic fixation system of claim 1, wherein the proximal end of the bone anchor is at or near the surface of a bone once in position.

4. The orthopaedic fixation system of claim 1, wherein the connector is an elbow.

5. The orthopaedic fixation system of claim 1, wherein an existing stabilizing rod is generally transverse to the arm.

6. An orthopaedic fixation system, comprising:
a bone anchor having proximal and distal ends and wherein the proximal end is substantially at the surface of a bone once in position; and
a connector having portion that engages with the bone anchor once in position and an arm that engages with an existing stabilizing rod.

7. The orthopaedic fixation system of claim 6, wherein the bone anchor includes outwardly advancing tangs or barbs to assist with fixation.

8. The orthopaedic fixation system of claim 6, wherein the connector is an elbow.

9. An orthopaedic fixation system, comprising:

a bone anchor having proximal and distal ends; and
an elbow having portion that engages with the bone anchor once in position and an arm that engages with an existing stabilizing rod.

10. The orthopaedic fixation system of claim 9, wherein the bone anchor includes outwardly advancing tangs or barbs to assist with fixation.

11. The orthopaedic fixation system of claim 9, wherein the proximal end of the bone anchor is substantially at the surface of a bone once in position.

12. The orthopaedic fixation system of claim 9, wherein an existing stabilizing rod is generally transverse to the arm.

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APPENDIX B

EVIDENCE

None.

APPENDIX C

RELATED PROCEEDINGS

None.